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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,660

09/28/2006

Satoshi Amano

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20529 7590 03/01/2011

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER

GHALI, ISIS A D

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

03/01/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	Application No. 10/587,660	Applicant(s) AMANO ET AL.	
	Examiner Isis A. Ghali	Art Unit 1611	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 23 February 2011 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☐ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☐ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: _____.
 Claim(s) objected to: _____.
 Claim(s) rejected: _____.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see continuation sheet.
 12. ☒ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). IDS filed 02/24/2011
 13. ☐ Other: _____.

/Isis A Ghali/
 Primary Examiner, Art Unit 1611

Continuation of 11. does NOT place the application in condition for allowance because:

Claims 7-8, 11-12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Kanios et al. US 6,905,016, in view of JP 2003-313122 ('122), or vice versa, JP '122 in view of Kanios.

Applicants argue that a proper case of prima facie obviousness has not been established because whether taken alone, or in combination, none of the cited references teach or suggest every element of the presently claimed subject matter. In addition, Applicants argue that the presently claimed subject matter is unexpectedly superior over the cited art for at least the reason that the claimed patch-containing pouches exhibit superior gas permeability and manageability. In contrast, Kanios is directed to a propanolol containing patch packaged in a pouch having a total thickness of about 1000 to 6250 micrometer. Kanios describes to pouches having an innermost layer with a surface that includes a Barex 210 which is not the same as the claimed patch- containing pouch, which comprises a multilayer film that comprises an innermost layer having a polyacrylonitrile surface, i.e., a polyacrylonitrile homopolymer surface. JP '122 merely describes a bisoprolol containing patch. However, JP'122 does not teach or suggest a pouch for encasing the patch described therein, let alone a pouch as claimed. Therefore, whether taken alone, or in combination, none of the cited references teach or suggest a patch-containing pouch, which comprises a multilayer film that comprises an innermost layer having a polyacrylonitrile surface, i.e., a polyacrylonitrile homopolymer surface. Kanios teaches away from the present invention

In response to these arguments, it is argued that Kanios teaches the thickness of layer 11 is from 0.5 mil to 2.5 mil which is equivalent to 12.7-63 micrometer and the thickness of layer 12 is from 0.2 to 3.0 mil which is equivalent to 5-76 μ m for layer 12. This teaching implies that the thickness of the multilayer film is from 17.7 to 139 micrometer and the reference suggested thinner and thicker widths may be employed. Therefore, the thickness taught by the prior art overlaps with the instant claims, unlike applicants assertion that the prior art teaches much higher thickness. In the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. See MPEP 2144.05 JR-5. In any event the prior art suggested thinner thicknesses. The examiner believes that every element of the claims are taught by the combined teachings of the prior art. JP '122 is relied upon for teaching bisoprolol suitable for transdermal delivery and for teaching specific claimed adhesive.

Further, one cannot attack the references individually when the obviousness is based on combination of the references. The claimed material of the pouch is taught by the combination of Kanios and JP 122, and not by Kanios alone that teaches Barex 210.

Kanios does not teach away because it is from the same field as applicant endeavor and is concerned with the same problem with which applicants are concerned. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant. The degree of teaching away will of course depend on the particular facts; in general, a reference will teach away if it suggests that the line of development flowing from the reference's disclosure is unlikely to be productive of the result sought by the applicant." In re Gurley, 27 F.3d 551,553 (Fed. Cir. 1994). The examiner believes that the present invention as a whole is taught by the combined teachings of the prior art and not made using hindsight of applicants' disclosure.

In addition, regarding applicant's arguments of unexpected results of the present invention, it is the examiner's position that the data in the specification regarding properties of the package are not unexpected results and therefore can not rebut prima facie obviousness. The examiner directs applicant's attention to MPEP 716.02 (a). "A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness of the claims at issue." In re Corkhill, 711 F.2d 1496, 266 USPQ 1006 (Fed.Cir. 1985). In Corkhill, the claimed combination showed an additive result when a diminished result would have been expected. Furthermore, the MPEP states, "Expected beneficial results are evidence of obviousness of a claimed invention, just as unexpected results are evidence of unobviousness thereof." In re Gershon, 372 F.2d 535, 538, 152 USPQ 602,604 (CCPA 1967). Kanios et al. teach their package prevents and controls degradation reactions that resulting from contamination of active material with packaging materials and improves stability of the drug during storage prior to use. The ultimate result of protecting the patch as desired by applicants is achieved by the package taught by the cited prior art.

Applicants further argue that JP '946 does not remedy the deficiencies of Kanios and JP '122 because whether taken alone or together, none of the cited references teach or suggest a patch-containing pouch, comprising: a multilayer film having a thickness of from 20 to 100 micrometer, as presently claimed.

In response to this argument, it is argued that the multilayer film package with the claimed thickness is taught by the combination of Kanios and JP 122. JP '946 is relied upon for the solely teaching of aluminum foil layer between the two layers of the package for the advantage of prevention of adsorption of active agent to the package and for protection against fall in the drug effect. The examiner believes that the present invention as a whole as defined by the claims is taught by the combination of the prior art and would have been prima facie obvious in the meaning of U.S.C. 103(a).